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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
12/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,012	BUCHARDT ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-36,38-41,43-45 and 47-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-36,38-41,43-45 and 47-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response filed 11/13/2009 is acknowledged.

Status of Claims

1. There is no change in the status of the claims. Claims 34-36,38-41,43-45,47-73 are pending.

Priority

Examiner maintains that the claimed subject matter is not entitled to the effective filing date 11/22/1993 of parent application 08/109591.

As explained in the preceding office action, the instant subject matter is directed to method of *in vivo* treatment having the following limitations:

- broad genus of compounds addressed as "polyamide nucleic acid oligomer containing neutral amide backbone linkages"
- treatment of living cells
- *in vivo* treatment

The parent application 08/108591 does not provide sufficient support for use of such broad genus of compounds, does not disclose use for *in vivo* treatment of living cells.

Consequently, the claimed subject matter is not entitled to the effective filing date 11/22/1993 of parent application 08/109591.

Response to arguments

Applicant offers discussion of the prosecution history; however, applicant provides no factual evidence (citation of pertinent sections of specification of the priority application) demonstrating support for the subject matter specified above. Examiner agrees that position on the benefit of priority of effective filing date 11/22/1993 of parent application 08/109591 has been revised in the preceding office action and invites applicant to provide factual evidence of support for the claimed subject matter in the priority application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2.(Maintained) Claims 34-36,41,48-51,58,59,65-68 are rejected under 35 U.S.C. 102(e) as anticipated by Summerton et al (US 5,142,047)

The instant claims are drawn to methods of treatment by *in vivo* administration of a polyamide nucleic acid oligomer containing neutral amide backbone linkages which is complementary to a target nucleic acid, under conditions wherein said oligomer engenders a biological response associated with said target. The claims specify that the administration is "extracellular". Claims 34-36,38-41,43-47 are directed to method of "treating living cells", whereas methods of claims 48-73 are directed to methods "comprising administering" said oligomer. Further, claims are directed to treating either cells, or mammals or organism (claims 34-36,38-40, claims 41-45,47, 58-64, and claims 65-73, respectively).

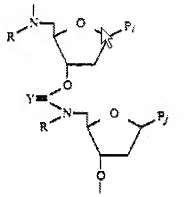
As the claims are directed either to extracellular administering *in vivo* or to treatment comprised of administering *in vivo*, it is Examiner's position that any reference teaching *in vivo* administration of oligomer as claimed will read on "extracellular administering *in vivo" or on "*treatment comprised of administering *in vivo*". As for the limitation "administering under conditions wherein said oligomer engenders a biological response associated with said target", again, it is Examiner's position that any reference teaching *in vivo* administration of oligomer as claimed (i.e., oligomer which is complementary to a target nucleic acid) is read as administering under conditions wherein said oligomer engenders a biological response associated with target nucleic acid to which the applied oligomer is complementary.

As such the following reference is considered to read on the invention as claimed.

Summerton et al (US 5,142,047)[1] teach therapeutic administration of polymer composition effective to bind to a single-stranded polynucleotide containing a

[1] Exemplary reference of multiple patents of the same applicant

preselected target sequence of bases. See Abstract. The composition is composed of linked-subunit heteromeric polymer molecules, such as polymer comprised of subunits "B" and connected by amide backbone linkages. A part of the polymer structure, for two moieties "B", oligomer B-B, is exemplified in col. 5:



wherein, for Y=O, the formula demonstrates an "oligomer containing neutral amide backbone linkage", and is a part of "polyamide nucleic acid oligomer" which contains "neutral amide backbone linkages".

The reference addresses use of the polymer composition for inhibiting biological activity of a single-stranded polynucleotide (col. 7, lines 45-47), disease-specific mRNA in particular (paragraph bridging columns 16-17). As the polymers of Summerton are binding compounds having desired binding activity to selected target sequence (col. 5, lines 1-7, and col. 16, bottom), and a target sequence is a single-stranded polynucleotide (col. 4, bottom), the oligomers of 5,142,047 read on oligomers administered as per the instant invention.

With respect to claims 35,49,66 directed to detecting biological response, as argued by applicant, disclosure of use to bind *in vivo* binding to target polynucleotides inherently teach monitoring the organism and detecting a biological response (response of 01/09/2008, p. 8, last full paragraph).

With respect to claims 51,59,68 specifying that the administered oligomer has sequence specificity to nucleic acid that regulates the expression or encodes a polypeptide, the reference teaches that the oligomers are complementary to single-stranded polynucleotides (col. 7, lines 45-47), disease-specific mRNA in particular (paragraph bridging columns 16-17) or genes (col. 17, line 53).

Response to arguments

Applicant's argument are mostly (except for the last paragraph) are copied from the Appeal Brief filed 06/04/2009 and have been addressed in the preceding Office action mailed 08/28/2009.

Applicant further argues that the claims are directed to compounds that contain neutral amide backbone linkages. As addressed before, Examiner maintains that the instant claims do have a structure of the compounds used; rather the claims use open language "containing" (which is equivalent to "comprising"): "containing neutral amide backbone linkages". As such the structure -O–CO-NR- in Summerton et al is viewed as containing that contain neutral amide backbone linkages (underlined) as instantly claimed.

3.(New) Claims 34-36,38-41,43-45,47-73 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Richelson et al. (US patent 6,472,209; effective filing date 10/17/1997).

As pointed out by applicant, the claims of Richelson et al. are copied in the instant application to provoke an interference. However, as the instantly claimed subject matter is not entitled to the effective filing date 11/22/1993 of parent application 08/109591 (see "Priority" section above), the effective filing date of the instant claims is 10/22/2003. Therefore, Richelson et al. is applied as prior art.

Response to arguments

See discussion of priority above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin/
Primary Examiner, Art Unit 1631